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09/990,874

11/21/2001

Wing L. Sung

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EXAMINER

RAO, MANJUNATH N

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 02/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/990,874

Applicant(s)

SUNG, WING L.

Examiner

Manjunath N. Rao, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2004 and 01 July 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-7,9-16,18-25,27-34,37-46,48,49 and 56-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-7,9-16,18-25,27-34,37-46,48,49 and 56-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>12/1/2003</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1-2, 4-7, 9-16, 18-25, 27-34, 37-46, 48-49, 56-71 are still at issue and are present for examination.

Election/Restrictions

Applicant's election with traverse of species No. 21, (i.e. a variant xylanase enzyme consisting of the following modification TrX-H-11D-ML-75A105H-118C-125A129E-144R161R in Paper No. 10 is acknowledged.

Applicants' amendments and arguments filed on 3-17-04 and 6-28-04, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. Examiner has specifically withdrawn the rejection of claim 50 under 35 U.S.C. 102(a) and (b) as anticipated by Kimura et al. (GenBank Accession No. Q9HFA4, 3-1-01) or Yoshino et al. (GenBank Accession No. Q12579, 11-1-1996) in view of the claim amendments to claim 1. Examiner acknowledges the amendments to specification by providing the appropriate SEQ ID NO.

Duty to Disclose

Examiner notes that applicants have filed multiple applications in the past some of which has matured into US patents, wherein said patents have claims drawn to xylanase variants similar to those claimed herein. Examiner reminds applicants that it their duty to disclose all such applications and patents. Examiner further requests that applicants not only disclose these in their FORM 1449 but provide a detailed description as to what

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type of variants have been claimed earlier and whether those patented variants read on any of the variants claimed in the instant application in order to aid the Examiner in his search for Double Patenting issues.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 and 2, 4-7, 9-16, 18-25, 27-34, 37-46, 48-49, 56-71 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is drawn to a modified xylanase comprising one or more than one substituted amino acid residue selected from the group consisting of an acidic amino acid at position 11, a non-polar amino acid at position- 116, a Cys at position 118, a first basic amino acid at position 144, and a second basic amino acid at position 161, said position determined from sequence alignment of said modified xylanase with *Trichoderma reesei* xylanase II amino acid sequence defined in SEQ ID NO:16. It is not clear from the claim as written whether the modified xylanase is limited to a variant of SEQ ID NO:16 comprising substitutions limited to one or more than one positions selected from the group indicated above or whether the “modified xylanase” comprises any xylanase with any amino acid sequence with the specific provision that said modified xylanase should consist of one or more substitution from the group of amino acid positions indicated above. Applicants, in their remarks, have argued that claim 1 is a

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generic claim as opposed to the Examiner's position that claim 1 is not a generic claim drawn to any xylanase variant but a specific variant of SEQ ID NO:16 comprising a modification at one or more positions specifically selected from the group of positions indicated above. Without acquiescing with the applicant's argument that claim 1 is a generic claim, Examiner has indeed treated claim 1 broadly as drawn to any modified xylanase wherein the modifications are not limited to the positions indicated above but comprising any number of changes in any amino acid positions with the specific provision that said modified xylanase should also consist of one or more than one substitution from the group of amino acid positions indicated above. Furthermore, it is also not clear to the Examiner whether the claimed xylanase continues to have the xylanase activity after said modification. All the following rejections are based on such broad interpretation of the claim. Examiner requests clarification from the applicant with regard to the breadth of the modification of the xylanase enzyme.

Claims 5, 10, 15, 19, 24, 28, 33, 37, 42, 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Above claims recite the phrase "derived from". The metes and bounds of this phrase in the context of the enzyme claimed in these claims are not clear to the Examiner. Literally, while the term "derived" means "to isolate from or obtain from a source", the above term could also mean "to arrive at by reasoning i.e., to deduce or infer" or also mean "to produce or obtain from another substance". Therefore, it is not clear to the Examiner either from the specification or from the claims as to what applicants mean by the above phrase. It is not

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clear to the Examiner whether the “derived from family 11 xylanase” encompasses specifically xylanase belonging to family 11 or whether it encompasses any xylanase belonging to any family and labeled as “derived from family 11 xylanase”. As applicants have not provided a definition for the above phrase, Examiner has interpreted the phrase broadly to mean that the starting enzyme (i.e., wild type enzyme) or the modified xylanase is not specifically limited to those belonging to “family 11”. Examiner has given the same interpretation while considering the claims for all other rejections.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 4-7, 9-16, 18-25, 27-34, 37-46, 48-49, 56-71 are rejected under 35

U.S.C. 112, first paragraph, because the specification, while being enabling for specific variants of xylanase with SEQ ID NO:16 comprising a substitution at one or more wherein said positions are limited to positions 10, 11, 27, 29, 75, 105, 116, 118, 125, 129, 144, 161 of SEQ ID NO:16 such that the modified xylanase continues to be classified in “Family 11” and continues to have xylanase activity and a method of using said xylanase (claim 48) in pulp manufacturing, does not reasonably provide enablement for any modified xylanase comprising a change in any amino acid position and one or more amino acid positions selected from the group 10, 11, 27, 29, 75, 105, 116, 118, 125, 129, 144, 161 of SEQ ID NO:16 irrespective of the fact that said modified xylanase continues to have xylanase activity or belongs to “family 11” of xylanases. The specification does

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not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 1-2, 4-7, 9-16, 18-25, 27-34, 37-46, 48-49, 56-71 are so broad as to encompass any modified xylanase comprising a change in any amino acid position and one or more amino acid positions selected from the group 10, 11, 27, 29, 75, 105, 116, 118, 125, 129, 144, 161 of SEQ ID NO:16 irrespective of the fact that said modified xylanase continues to have xylanase activity or belongs to "family 11" of xylanases. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of xylanases broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to a modified xylanase of SEQ ID NO:16 comprising specific substitutions at positions 10, 11, 27, 29, 75, 105, 116, 118, 125, 129,

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144, 161 with specific amino acids. It would require undue experimentation of the skilled artisan to make and use the claimed polypeptides. The specification is limited to teaching the use of SEQ ID NO:16 as parent xylanase wherein amino acids at specific positions such as 10, 11, 27, 29, 75, 105, 116, 118, 125, 129, 144, 161 can be substituted with other specific amino acids but provides no guidance with regard to the making of variants and mutants or with regard to other uses comprising modifying any or all amino acids in SEQ ID NO:16. In view of the great breadth of the claim, amount of experimentation required to make the claimed polypeptides, the lack of guidance, working examples, and unpredictability of the art in predicting function from a polypeptide primary structure (e.g., see Ngo et al. in *The Protein Folding Problem and Tertiary Structure Prediction*, 1994, Merz et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495), the claimed invention would require undue experimentation. As such, the specification fails to teach one of ordinary skill how to use the full scope of the polypeptides encompassed by this claim.

While enzyme isolation techniques, recombinant and mutagenesis techniques are known, and it is routine in the art to screen for multiple substitutions or multiple modifications as encompassed by the instant claims, the specific amino acid positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

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The specification does not support the broad scope of the claims which encompass all modifications and fragments of any xylanase or SEQ ID NO:16 because the specification does not establish: (A) regions of the protein structure which may be modified without affecting xylanase activity; (B) the general tolerance of xylanases to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residue in the sequence with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including xylanases with an enormous number of amino acid modifications or modification of SEQ ID NO: 16. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of xylanase variants having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claims 1-2, 4-7, 9-16, 18-25, 27-34, 37-46, 48-49, 56-71 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Claims 1-2, 4-7, 9-16, 18-25, 27-34, 37-46, 48-49, 56-71 are directed to variants of xylanases comprising modified xylanases wherein any amino acid position is modified by at least one of deletion, addition, insertion and substitution with any other amino acid with the provision that said variants also comprises specific substitutions at one or more positions from the group consisting of positions 10, 11, 27, 29, 75, 105, 116, 118, 125, 129, 144, 161. Above claims are rejected under this section of 35 USC 112 because the claims are directed to a genus of polypeptides derived from SEQ ID NO:16 including modified polypeptide sequences comprising specific substitutions at positions 10, 11, 27, 29, 75, 105, 116, 118, 125, 129, 144, 161, that have not been disclosed in the specification. No description has been provided of the modified polypeptide sequences encompassed by the claim. No information, beyond the characterization of SEQ ID NO:16 and the specific positions 10, 11, 27, 29, 75, 105, 116, 118, 125, 129, 144, 161 that can be substituted with other specific amino acids has been provided by applicants which would indicate that they had possession of the claimed genus of modified polypeptides. The specification does not contain any disclosure of the structure of all the polypeptide sequences derived from SEQ ID NO:16, including fragments and variants within the scope of the claimed genus. The genus of polypeptides claimed is a large variable genus including peptides which can have a wide variety of structures. Therefore many structurally unrelated polypeptides are encompassed within the scope of these claims. The specification discloses only a single species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably

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conclude that applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 1-2, 4-7, 9-16, 18-25, 27-34, 37-46, 48-49, 56-71 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-2, 4-7, 9-16, 18-25, 27-34, 37-46, 48-49, 56-71 are directed to “modified xylanase” (however the claim does not make it unequivocal that said modified xylanase continues to have the xylanase activity after said modification) wherein any amino acid position is modified by at least one of deletion, addition, insertion and substitution with any other amino acid with the provision that said variants also comprises specific substitutions at one or more positions from the group consisting of positions 10, 11, 27, 29, 75, 105, 116, 118, 125, 129, 144, 161. Above claims are rejected under this section of 35 USC 112 because the claims are directed to a genus of polypeptides derived from SEQ ID NO:16 including modified polypeptide sequences comprising specific substitutions at positions 10, 11, 27, 29, 75, 105, 116, 118, 125, 129, 144, 161, that have not been disclosed in the specification. No description has been provided of the modified polypeptide sequences encompassed by the claim. No

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information, beyond the characterization of SEQ ID NO:16 as the wild type or native xylanase has been provided by applicants which would indicate that they had possession of the claimed genus of modified polypeptides. The specification does not contain any disclosure of the function of all the polypeptide sequences derived from SEQ ID NO:16, including fragments and variants within the scope of the claimed genus. The genus of polypeptides claimed is a large variable genus including peptides which can have a wide variety of functions or no activity at all. Therefore many functionally unrelated polypeptides are encompassed within the scope of these claims. The specification discloses only a single species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov. (Reiteration of the function in the claims may overcome this rejection).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the

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international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 4-7, 9-16, 18-25, 27-34, 37-46, 48, 56-71 are rejected under 35

U.S.C. 102(e) as being anticipated by NRC of Canada (NRC) et al. (WO 01/92487 A2, Dec 6, 2001, filed in English, designating US, filed on 5-31-2001 with priority benefit to US 60/213,803, 5-31-2000) or Wing Sung (US20030166236 A1, published 9-4-03, with priority date 5-31-2001). This rejection is based upon the public availability of a printed publication. Claims 1-2, 4-7, 9-16, 18-25, 27-34, 37-46, 48-49, 56-71 of the instant application are drawn to a modified xylanase comprising at least one or more than one substituted amino acid residue at a position selected from the group consisting of an acidic amino acid 11, a non-polar amino acid at position 116, a Cys at position 118, a basic amino acid at positions 144 and 161, said positions determined from sequence alignment of said modified xylanase with *T.reesei* xylanase amino acid sequence defined in SEQ ID NO:16, wherein the modified xylanase further comprises substitutions at positions 10, 27, 29, 75, 105, 125, 129, and exhibits improved characteristics corresponding to native xylanase and is used for an industrial process such as paper pulp manufacture.

NRC discloses an identical xylanase which encompasses a variant comprising a substitution at positions 144, 161 with a basic amino acid, (H144R and Q161R, see page 22, last entry in Table 2) said position determined from sequence alignment of said modified xylanase with *T.reesei* xylanase amino acid sequence defined in SEQ ID NO:16, wherein the modified xylanase exhibits improved characteristics (see) and its use in a industrial process such as paper pulp manufacture. Thus NRC anticipate claims 1-2, 4-7, 9-16, 18-25, 27-34, 37-46, 48, 56-71 of this application as written.

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On similar lines Wing Sung discloses an identical xylanase which encompasses a variant comprising a substitution at positions 144, 161 with a basic amino acid, (H144R and Q161R, see page10, Column 1) said position determined from sequence alignment of said modified xylanase with *T.reesei* xylanase amino acid sequence defined in SEQ ID NO:16, wherein the modified xylanase exhibits improved characteristics (see) and its use in a industrial process such as paper pulp manufacture. Thus Wing Sung anticipates claims 1-2, 4-7, 9-16, 18-25, 27-34, 37-46, 48, 56-71 of this application as written.

In response to the previous Office action, applicants have traversed the above rejection arguing that the publication date is 12-6-01 which date is after the filing date of the instant application and also that the reference inventor is the same the same as in the instant application. Applicants also argue that since the WO document designates the US, the reference cannot be considered as filed by another and therefore the WO reference is not applicable. Examiner respectfully disagrees. This is because, while the publication date of the reference is 12-6-01, it was filed after Nov. 29, 2000 because of which the reference gets the benefit of its priority application filed in the US as a provisional application dated 5-31-2000. Therefore, for all practical purposes, the priority date of the reference (5-31-2000) is prior to the effective filing date of the instant application (11-21-2001) and is a valid reference under 35 U.S.C. 102(e) (see part 2 of the statute above).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

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and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 4-5 and 6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 5 and 6 of U.S. application no.10/307441. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim, because the examined claim is either anticipated by, or would have been obvious over the reference claim. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi* 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 1, 2, 4, 5-6 of the instant application and claims 1, 2, 5-6 of the reference patent are both directed to variants of xylanase having an amino acid sequence in which the amino acid at one or more positions 144 and 161 are substituted with another by aligning the sequence with SEQ ID NO:16, wherein said xylanase is from family 11 and from *Trichoderma reesei*. The only difference between the two set of claims is that the instant claims are drawn to a variant wherein the substituted amino acids at positions 144 and 161 are specifically a basic amino acid as opposed to no such

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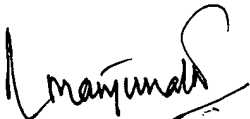
limitation in the reference application. However, the reference application teaches in the specification that mutants may be constructed by substituting a basic amino acid at position 144 or 161 (see page 10 column 1 of the published application). Among the different positions claimed in the instant application and in the reference application the amino acid that is being substituted are identical to one another. The portion of the specification (and the claims) in the reference application that supports the recited amino acid positions includes the embodiments (substitutions with a basic amino acid) that would anticipate the positions claimed in claims 1, 2, 4-6 herein. Claims of the instant application listed above cannot be considered patentably distinct over claims 1, 2 5-6 of the reference application when there is specifically recited embodiment that would anticipate mainly claims 1-2, 4-6 of the instant application. Alternatively, claims 1-2, 4-6 cannot be considered patentably distinct over claims 1, 2, 5-6 of the reference application when there is specifically disclosed embodiment in the reference application that supports claims 1, 2, 5-6 of that application and falls within the scope of claims 1-2, 4-6 herein because it would have been obvious to one having ordinary skill in the art to modify claims 1-2, 5-6 of the reference application by selecting the specifically disclosed embodiment that supports those claims i.e., a variant comprising a substitution at one or more positions of 144 and 161 wherein said substitution comprise a basic amino acid. One of ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment within claims 1, 2, 5-6 of the reference application.

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Conclusion

None of the claims are allowable.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 571-272-0939. The Examiner can normally be reached on 7.00 a.m. to 3.30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



Manjunath N. Rao, Ph.D.
Primary Examiner
Art Unit 1652

February 6, 2006